# PART 70 SIGNIFICANT SOURCE MODIFICATION INDIANA DEPARTMENT of ENVIRONMENTAL MANAGEMENT OFFICE OF AIR QUALITY and VIGO COUNTY AIR POLLUTION CONTROL

### Pfizer Inc 100 Pfizer Drive Terre Haute, Indiana 47802

(herein known as the Permittee) is hereby authorized to construct and operate subject to the conditions contained herein, the emission units described in Section A (Source Summary) of this approval.

This approval is issued in accordance with 326 IAC 2 and 40 CFR Part 70 Appendix A and contains the conditions and provisions specified in 326 IAC 2-7 as required by 42 U.S.C. 7401, et. seq. (Clean Air Act as amended by the 1990 Clean Air Act Amendments), 40 CFR Part 70.6, IC 13-15 and IC 13-17.

Source Modification No.: 167-15658-00013	
Original signed by George M. Needham Issued by: George M. Needham, Director Vigo County Air Pollution Control	Issuance Date: October 17, 2002

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### SECTION A SOURCE SUMMARY

This approval is based on information requested by the Indiana Department of Environmental Management (IDEM), Office of Air Quality (OAQ) and Vigo County Air Pollution Control (VCAPC). The information describing the emission units contained in conditions A.1 through A.2 is descriptive information and does not constitute enforceable conditions. However, the Permittee should be aware that a physical change or a change in the method of operation that may render this descriptive information obsolete or inaccurate may trigger requirements for the Permittee to obtain additional permits or seek modification of this approval pursuant to 326 IAC 2, or change other applicable requirements presented in the permit application.

### A.1 General Information [326 IAC 2-7-4(c)] [326 IAC 2-7-5(15)]

The Permittee owns and operates a stationary batch pharmaceutical manufacturing operation facility.

Responsible Official: Plant Manager

Source Address: 100 Pfizer Drive, Terre Haute, Indiana 47802 Mailing Address: P.O. Box 88, Terre Haute, Indiana 47808

General Source Phone Number: (812)299-2121

SIC Code: 2833 County Location: Vigo

Source Location Status: Attainment for all criteria pollutants

Source Status: Part 70 Permit Program

Major Source, under PSD Rules;

Major Source, Section 112 of the Clean Air Act

A.2 Emission Units and Pollution Control Equipment Summary [326 IAC 2-7-4(c)(3)]

[326 IAC 2-7-5(15)]

This stationary source is approved for the following:

Pfizer Inc has requested a Significant Source Modification for boiler #8, regarding an enforceable limit on the emission of hydrogen chloride (HCl). This approval establishes a limitation on the chlorine content of coal fed to boiler #8 which, combined with the miscellaneous emissions described in Condition A.3, will restrict Pfizer Inc's potential emissions to below the minimum thresholds for a major source for Hazardous Air Pollutants (HAP).

### A.3 Specifically Regulated Insignificant Activities [326 IAC 2-7-1(21)] [326 IAC 2-7-4(c)] [326 IAC 2-7-5(15)]

This stationary source also includes the following insignificant activities which are specifically regulated, as defined in 326 IAC 2-7-1(21). Potential emissions of HCI from these insignificant activities are referred to, for purposes of this approval, as the "miscellaneous emissions":

- (a) The Bioprocessing operations use HCl to regenerate the ion exchange towers.
- (b) The laboratory operations use HCl as a reagent in very small quantities.
- (c) The cleaning and maintenance operations use HCl for heavy duty cleaning in very small quantities. HCl is also occasionally used for floor etching in insulin and in Building 551.
- (d) The wastewater treatment plant does not actually use HCl in the wastewater treatment activities. HCl is present in the wastewater in small concentrations from Bioprocessing.

### A.4 Part 70 Permit Applicability [326 IAC 2-7-2]

This stationary source is required to have a Part 70 permit by 326 IAC 2-7-2 (Applicability) because:

- (a) It is a major source, as defined in 326 IAC 2-7-1(22);
- (b) It is a source in a source category designated by the United States Environmental Protection Agency (U.S. EPA) under 40 CFR 70.3 (Part 70 Applicability).

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### SECTION B GENERAL CONSTRUCTION CONDITIONS

### B.1 Definitions [326 IAC 2-7-1]

Terms in this permit shall have the definition assigned to such terms in the referenced regulation. In the absence of definitions in the referenced regulation, the applicable definitions found in the statutes or regulations (IC 13-11, 326 IAC 1-2 and 326 IAC 2-7) shall prevail.

### B.2 Effective Date of the Permit [IC13-15-5-3]

Pursuant to IC 13-15-5-3, this approval becomes effective upon its issuance.

### B.3 Significant Source Modification [326 IAC 2-7-10.5(h)]

Since no construction is planned under the Significant Source Modification, this document shall also become the approval to operate effective upon its issuance.

- (a) The attached affidavit of construction shall be submitted to Vigo County Air Pollution Control (VCAPC) verifying that the emission units were constructed as proposed in the application. The emissions units covered in the Significant Source Modification approval may begin operating on the date the affidavit of construction is postmarked or hand delivered to VCAPC if constructed as proposed.
- (b) The Permittee shall receive an Operation Permit Validation Letter from the Director of VCAPC.
- (c) In the event that the Part 70 application is being processed at the same time as this application, the following additional procedures shall be followed for obtaining the right to operate:
  - (1) If the Part 70 draft permit has not gone on public notice, then the change/addition covered by the Significant Source Modification will be included in the Part 70 draft.
  - (2) If the Part 70 permit has gone through final EPA proposal and would be issued ahead of the Significant Source Modification, the Significant Source Modification will go through a concurrent 45 day EPA review. Then the Significant Source Modification will be incorporated into the final Part 70 permit at the time of issuance.
  - (3) If the Part 70 permit has gone through public notice, but has not gone through final EPA review and would be issued after the Significant Source Modification is issued, then the Modification would be added to the proposed Part 70 permit, and the Title V permit will issued after EPA review.

### B.4 Local Agency Requirement

This approval shall also be considered a local approval by VCAPC. No additional application is needed.

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### **SECTION C**

### **GENERAL OPERATION CONDITIONS**

### C.1 Certification [326 IAC 2-7-4(f)][326 IAC 2-7-6(1)][326 IAC 2-7-5(3)(C)]

- (a) Where specifically designated by this permit or required by an applicable requirement, any application form, report, or compliance certification submitted shall contain certification by a responsible official of truth, accuracy, and completeness. This certification shall state that, based on information and belief formed after reasonable inquiry, the statements and information in the document are true, accurate, and complete.
- (b) One (1) certification shall be included, using the attached Certification Form, with each submittal requiring certification.
- (c) A responsible official is defined at 326 IAC 2-7-1(34).

### C.2 Permit Amendment or Modification [326 IAC 2-7-11] [326 IAC 2-7-12]

- (a) Permit amendments and modifications are governed by the requirements of 326 IAC 2-7-11 or 326 IAC 2-7-12 whenever the Permittee seeks to amend or modify this permit.
- (b) Any application requesting an amendment or modification of this permit shall be submitted to:

Indiana Department of Environmental Management Permits Branch, Office of Air Quality 100 North Senate Avenue, P.O. Box 6015 Indianapolis, Indiana 46206-6015

and

Vigo County Air Pollution Control 103 South Third Street Terre Haute, Indiana 47807

Any such application shall be certified by the "responsible official" as defined by 326 IAC 2-7-1(34).

(c) The Permittee may implement administrative amendment changes addressed in the request for an administrative amendment immediately upon submittal of the request. [326 IAC 2-7-11(c)(3)]

### C.3 Opacity [326 IAC 5-1]

Pursuant to 326 IAC 5-1-2 (Opacity Limitations), except as provided in 326 IAC 5-1-3 (Temporary Alternative Opacity Limitations), opacity shall meet the following, unless otherwise stated in this permit:

- (a) Opacity shall not exceed an average of forty percent (40%) in any one (1) six (6) minute averaging period as determined in 326 IAC 5-1-4.
- (b) Opacity shall not exceed sixty percent (60%) for more than a cumulative total of fifteen (15) minutes (sixty (60) readings as measured according to 40 CFR 60, Appendix A, Method 9 or fifteen (15) one (1) minute nonoverlapping integrated averages for a continuous opacity monitor) in a six (6) hour period.

### C.4 Fugitive Dust Emissions [326 IAC 6-4]

The Permittee shall not allow fugitive dust to escape beyond the property line or boundaries of the property, right-of-way, or easement on which the source is located, in a manner that would violate 326 IAC 6-4 (Fugitive Dust Emissions). 326 IAC 6-4-2(4) is not federally enforceable.

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### C.5 Operation of Equipment [326 IAC 2-7-6(6)]

Except as otherwise provided by statute or rule, or in this permit, all air pollution control equipment listed in this permit and used to comply with an applicable requirement shall be operated at all times that the emission units vented to the control equipment are in operation.

### C.6 Stack Height [326 IAC 1-7]

The Permittee shall comply with the applicable provisions of 326 IAC 1-7 (Stack Height Provisions), for all exhaust stacks through which a potential (before controls) of twenty-five (25) tons per year or more of particulate matter or sulfur dioxide is emitted by using good engineering practices (GEP) pursuant to 326 IAC 1-7-3.

### Compliance Requirements [326 IAC 2-1.1-11]

### C.7 Compliance Requirements [326 IAC 2-1.1-11]

The commissioner may require stack testing, monitoring, or reporting at any time to assure compliance with all applicable requirements. Any monitoring or testing shall be performed in accordance with 326 IAC 3 or other methods approved by the commissioner or the U. S. EPA.

### Compliance Monitoring Requirements [326 IAC 2-7-5(3)] [326 IAC 2-7-6(1)]

### C.8 Compliance Monitoring [326 IAC 2-7-5(3)] [326 IAC 2-7-6(1)]

If required by Section D, all monitoring and record keeping requirements shall be implemented when operation begins. The Permittee shall be responsible for installing any necessary equipment and initiating any required monitoring related to that equipment.

### Corrective Actions and Response Steps [326 IAC 2-7-5] [326 IAC 2-7-6][326 IAC 2-7-16]

### C.9 Emergency Provisions [326 IAC 2-7-16]

- (a) An emergency, as defined in 326 IAC 2-7-1(12), is not an affirmative defense for an action brought for noncompliance with a federal or state health-based emission limitation, except as provided in 326 IAC 2-7-16.
- (b) An emergency, as defined in 326 IAC 2-7-1(12), constitutes an affirmative defense to an action brought for noncompliance with a health-based or technology-based emission limitation if the affirmative defense of an emergency is demonstrated through properly signed, contemporaneous operating logs or other relevant evidence that describe the following:
  - (1) An emergency occurred and the Permittee can, to the extent possible, identify the causes of the emergency;
  - (2) The permitted facility was at the time being properly operated;
  - (3) During the period of an emergency, the Permittee took all reasonable steps to minimize levels of emissions that exceeded the emission standards or other requirements in this permit;
  - (4) For each emergency lasting one (1) hour or more, the Permittee notified IDEM, OAQ, and VCAPC within four (4) daytime business hours after the beginning of the emergency, or after the emergency was discovered or reasonably should have been discovered:

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Telephone Number: 1-800-451-6027 (ask for Office of Air Quality,

Compliance Section), or

Telephone Number: 317-233-5674 (ask for Compliance Section)

Facsimile Number: 317-233-5967

### **VCAPC**

Telephone Number. 812-462-3433 Facsimile Number. 812-462-3433

(5) For each emergency lasting one (1) hour or more, the Permittee submitted the attached Emergency Occurrence Report Form or its equivalent, either by mail or facsimile to:

Indiana Department of Environmental Management Compliance Branch, Office of Air Quality 100 North Senate Avenue, P. O. Box 6015 Indianapolis, Indiana 46206-6015

and

Vigo County Air Pollution Control 103 South Third Street Terre Haute. Indiana 47807

within two (2) working days of the time when emission limitations were exceeded due to the emergency.

The notice fulfills the requirement of 326 IAC 2-7-5(3)(C)(ii) and must contain the following:

- (A) A description of the emergency;
- (B) Any steps taken to mitigate the emissions; and
- (C) Corrective actions taken.

The notification which shall be submitted by the Permittee does not require the certification by the "responsible official" as defined by 326 IAC 2-7-1(34).

- (6) The Permittee immediately took all reasonable steps to correct the emergency.
- (c) In any enforcement proceeding, the Permittee seeking to establish the occurrence of an emergency has the burden of proof.
- (d) This emergency provision supersedes 326 IAC 1-6 (Malfunctions). This permit condition is in addition to any emergency or upset provision contained in any applicable requirement.
- (e) IDEM, OAQ, and VCAPC may require that the Preventive Maintenance Plans required under 326 IAC 2-7-4-(c)(10) be revised in response to an emergency.
- (f) Failure to notify IDEM, OAQ, and VCAPC by telephone or facsimile of an emergency lasting more than one (1) hour in accordance with (b)(4) and (5) of this condition shall constitute a violation of 326 IAC 2-7 and any other applicable rules.
- (g) Operations may continue during an emergency only if the following conditions are met:
  - (1) If the emergency situation causes a deviation from a technology-based limit, the Permittee may continue to operate the affected emitting facilities during the

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emergency provided the Permittee immediately takes all reasonable steps to correct the emergency and minimize emissions.

- (2) If an emergency situation causes a deviation from a health-based limit, the Permittee may not continue to operate the affected emissions facilities unless:
  - (A) The Permittee immediately takes all reasonable steps to correct the emergency situation and to minimize emissions; and
  - (B) Continued operation of the facilities is necessary to prevent imminent injury to persons, severe damage to equipment, substantial loss of capital investment, or loss of product or raw materials of substantial economic value.

Any operation shall continue no longer than the minimum time required to prevent the situations identified in (g)(2)(B) of this condition.

### Record Keeping and Reporting Requirements [326 IAC 2-7-5(3)] [326 IAC 2-7-6][326 IAC 2-7-19]

### C.10 General Record Keeping Requirements [326 IAC 2-7-5(3)][326 IAC 2-7-6]

- (a) Records of all required data, reports and support information shall be retained for a period of at least five (5) years from the date of monitoring sample, measurement, report, or application. These records shall be kept at the source location for a minimum of three (3) years. The records may be stored elsewhere for the remaining two (2) years as long as they are available upon request. If the Commissioner or VCAPC makes a request for records to the Permittee, the Permittee shall furnish the records to the Commissioner or VCAPC within a reasonable time.
- (b) Unless otherwise specified in this permit, all record keeping requirements not already legally required shall be implemented within ninety (90) days of permit issuance.

### C.11 General Reporting Requirements [326 IAC 2-7-5(3)(C)]

(a) The reports required by conditions in Section D of this permit shall be submitted to:

Indiana Department of Environmental Management Compliance Data Section, Office of Air Quality 100 North Senate Avenue, P. O. Box 6015 Indianapolis, Indiana 46206-6015

and

Vigo County Air Pollution Control 103 South Third Street Terre Haute, Indiana 47807

- (b) Unless otherwise specified in this permit, any notice, report, or other submission required by this permit shall be considered timely if the date postmarked on the envelope or certified mail receipt, or affixed by the shipper on the private shipping receipt, is on or before the date it is due. If the document is submitted by any other means, it shall be considered timely if received by IDEM, OAQ, and VCAPC on or before the date it is due.
- (c) Unless otherwise specified in this permit, all reports required in Section D of this permit shall be submitted within thirty (30) days of the end of the reporting period. All reports do require the certification by the "responsible official" as defined by 326 IAC 2-7-1(34).
- (d) The first report shall cover the period commencing on the date of issuance of this permit and ending on the last day of the reporting period. Reporting periods are based on calendar years.

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### Facility Description [326 IAC 2-7-5(15)]

(a) One (1) subbituminous coal fired boiler, identified as boiler #8, with No. 1 distillate fuel, No. 6 residual oil, natural gas, and liquefied petroleum gas as backup fuel. Maximum capacity of 150 million (MM) Btu per hour heat input when using coal, No. 1, and No. 6, and 40 million (MM) Btu per hour heat input capacity when using natural gas, and liquefied petroleum gas. Emissions exhausting to stack 1.

(The information describing the process contained in this facility description box is descriptive information and does not constitute enforceable conditions.)

### Emission Limitations and Standards [326 IAC 2-7-5(1)]

### D.1.1 Fuel Use Limitation [326 IAC 2-7-10.5(d)(5)

- (a) The Chlorine content of the coal delivered to boiler #8 shall not exceed 9.43 tons per 12-consecutive month period, with compliance determined at the end of each month.
- (d) This limitation, in combination with the miscellaneous emissions, restricts the potential emissions of HCl below 10 tons per year. Therefore, Pfizer Inc is not considered a major source for Hazardous Air Pollutants (HAPs) and is not subject to 40 CFR Part 63, Subpart GGG National Emission Standards for Pharmaceuticals Production, or any other NESHAP.

### **Compliance Determination Requirements**

### D.1.2 Hydrogen Chloride (HCI) Emissions and Chlorine Content

Pursuant to 326 IAC 2-7-6, the Permittee shall demonstrate that the chlorine content of coal delivered to Boiler #8 does not exceed the limitation set in Condition D.1.1 (9.43 tons per 12-consecutive month period). Compliance shall be determined utilizing one of the following options:

- (a) Coal sampling and analysis shall be performed using one of the following procedures:
  - (1) Minimum Coal Sampling Requirements and Analysis Methods [326 IAC 3-7-2(b)(3)]:
    - (A) The coal sample acquisition point shall be at a location where representative samples of the total coal flow to be combusted by the facility or facilities may be obtained. A single as-bunkered or as-burned sampling station may be used to represent the coal to be combusted by multiple facilities using the same stockpile feed system;
    - (B) Coal shall be sampled at least three (3) times per day and at least one (1) time per eight (8) hour period unless no coal is bunkered during the preceding eight (8) hour period;
    - (C) Minimum sample size shall be five hundred (500) grams;
    - (D) Samples shall be composited and analyzed at the end of each calendar month;
  - (2) Sample and analyze the coal pursuant to 326 IAC 3-7-2(a); or
  - (3) Sample and analyze the coal pursuant to 326 IAC 3-7-3;
  - (4) The Chlorine content of coal samples shall be determined in accordance with either the procedures specified in ASTM D2361, Standard Test Methods for

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Chlorine in Coal, or the procedures specified in ASTM D4208, Standard Test Method for Total Chlorine in Coal by the Oxygen Bomb Combustion/Ion Selective Electrode Method.

Preparation of the coal sample heat content analysis under any of these three methods shall be determined pursuant to 326 IAC 3-7-2(c), (d), and (e).

A determination of noncompliance pursuant to any of the methods specified in (a) above shall not be refuted by evidence of compliance pursuant to the other method.

### Record Keeping and Reporting Requirements [326 IAC 2-7-5(3)] [326 IAC 2-7-19]

### D.1.3 Record Keeping Requirements

- (a) To document compliance with Condition D.1.1, the Permittee shall maintain records for Boiler #8 in accordance with (1) through (5) below. Records maintained for (1) through (5) shall be taken monthly and shall be complete and sufficient to establish compliance with the limit on chlorine content of coal combusted in boiler #8.
  - (1) Calendar dates covered in the compliance determination period;
  - (2) Actual coal usage since last compliance determination period;
  - (3) Chlorine content, heat content, and ash content (as received basis);
  - (4) Chlorine input during compliance period
  - (5) Hydrogen Chloride emission rates.
- (b) Pursuant to 326 IAC 3-7-5(a), the Permittee has developed a standard operating procedure (SOP) to be followed for sampling, handling, analysis, quality control, quality assurance, and data reporting of the information collected pursuant to 326 IAC 3-7-2 through 326 IAC 3-7-3. Any revision to the SOP shall be submitted to IDEM, OAQ and VCAPC.
- (c) All records shall be maintained in accordance with Section C General Record Keeping Requirements, of this permit.

### D.1.4 Reporting Requirements

A quarterly summary of the information to document compliance with Condition D.1.1 shall be submitted to the addresses listed in Section C - General Reporting Requirements, of this permit, using the reporting forms located at the end of this permit, or their equivalent, within thirty (30) days after the end of the quarter being reported. The report submitted by the Permittee does require the certification by the "responsible official" as defined by 326 IAC 2-7-1(34).

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### **OFFICE OF AIR QUALITY COMPLIANCE DATA SECTION** and **VIGO COUNTY AIR POLLUTION CONTROL**

### **PART 70 SOURCE MODIFICATION CERTIFICATION**

Source Name: Pfizer Inc

Source Address: 100 Pfizer Drive, Terre Haute, Indiana 47802 P.O. Box 88, Terre Haute, Indiana 47808 Mailing Address:

Source Modification No.:167-15658-00013			
This certification shall be included when submitting monitoring, testing reports/results or other documents as required by this approval.			
Please check what document is being certified:			
9 Test Result (specify)			
9 Report (specify)			
9 Notification (specify)			
9 Affidavit (specify)			
9 Other (specify)			
I certify that, based on information and belief formed after reasonable inquiry, the statements and information in the document are true, accurate, and complete.			
Signature:			
Printed Name:			
Title/Position:			
Date:			

Pfizer Inc Terre Haute, Indiana Permit Reviewer: Darren Woodward

> Date: Phone:

# INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT OFFICE OF AIR QUALITY COMPLIANCE DATA SECTION and VIGO COUNTY AIR POLLUTION CONTROL

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Part 70 Source Modification Quarterly Report					
Source Name: Source Address: Mailing Address: Source Modification No.: Facility: Limit:	P.O. Box 88, Terre I 167-15658-00013 Boiler #8 9.43 tons of Chloring	100 Pfizer Drive, Terre Haute, Indiana 47802 P.O. Box 88, Terre Haute, Indiana 47808 167-15658-00013			
	YEAR:				
Month	Tons of Chlorine in the Coal This Month	Tons of Chlorine in the Coal Previous 11 Months	Tons of Chlorine in the Coal 12 Month Total		
Month 1					
Month 2					
Month 3					
Devia Submitted Title / Pos Signature:	9Deviation/s occur ation has been reported or by:	urred in this quarter. rred in this quarter. n:			

## Indiana Department of Environmental Management Office of Air Quality and Vigo County Air Pollution Control

Addendum to the Technical Support Document for Significant Source Modification

Source Name: Pfizer Inc

Source Location: 100 Pfizer Drive, Terre Haute, Indiana 47802

County: Vigo SIC Code: 2833

Operation Permit No.: 167-15658-00013
Permit Reviewer: Darren Woodward

On September 13, 2002, Vigo County Air Pollution Control (VCAPC) had a notice published in the Terre Haute Tribune Star, Terre Haute, Indiana, stating that Pfizer Inc had applied for a Significant Source Modification for an enforceable limit on the Chlorine content of coal delivered to boiler #8. The notice also stated that VCAPC proposed to issue a permit for this operation and provided information on how the public could review the proposed permit and other documentation. Finally, the notice informed interested parties that there was a period of thirty (30) days to provide comments on whether or not this permit should be issued as proposed.

On September 23, 2002, Pfizer Inc submitted comments on the proposed Significant Source Modification. The summary of the comments is as follows:

### **Table of Contents:**

### Comment 1:

The numbering of A.3 and A.4 are reversed (but text is correct).

### **Response to Comment 1:**

The numbering was corrected.

A.4 A.3. Specifically Regulated Insignificant Activities [326 IAC 2-7-1(21)] [326 IAC 2-7-4(c)]

A.3 A.4. Part 70 Permit Applicability [326 IAC 2-7-2]

### Comment 2:

Compliance Monitoring Requirements citation should be 326 IAC 2-7-5(3) instead of 2-7-5(1).

### **Response to Comment 2:**

The citation was corrected.

Compliance Monitoring Requirements [326 IAC 2-7-5(1)] [326 IAC 2-7-6(1)]

Compliance Monitoring Requirements [326 IAC 2-7-5(1)(3)] [326 IAC 2-7-6(1)]

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### Comment 3:

C.10 should reference 326 IAC 2-7-16.

### **Response to Comment 3:**

Reference was added.

### Corrective Actions and Response Steps [326 IAC 2-7-5] [326 IAC 2-7-6]

- C.10 Emergency Provisions
- C.11 Actions Related to Noncompliance Demonstrated by a Stack Test [326 IAC 2-7-5]

### Corrective Actions and Response Steps [326 IAC 2-7-5] [326 IAC 2-7-6][326 IAC 2-7-16]

- C.10 Emergency Provisions [326 IAC 2-7-16]
- C.11 Actions Related to Noncompliance Demonstrated by a Stack Test [326 IAC 2-7-5] [326 IAC 2-7-6]

### Comment 4:

C.11 should also reference 326 IAC 2-7-6.

### **Response to Comment 4:**

Reference was added.

### Corrective Actions and Response Steps [326 IAC 2-7-5] [326 IAC 2-7-6]

- C.10 Emergency Provisions
- C.11 Actions Related to Noncompliance Demonstrated by a Stack Test [326 IAC 2-7-5]

### Corrective Actions and Response Steps [326 IAC 2-7-5] [326 IAC 2-7-6][326 IAC 2-7-16]

- C.10 Emergency Provisions [326 IAC 2-7-16]
- C.11 Actions Related to Noncompliance Demonstrated by a Stack Test [326 IAC 2-7-5] [326 IAC 2-7-6]

### Comment 5:

C.12 add reference 326 IAC 2-7-6.

### **Response to Comment 5:**

Reference was added.

### Record Keeping and Reporting Requirements [326 IAC 2-7-5(3)][ [326 IAC 2-7-19]

- C.12 General Record Keeping Requirements [326 IAC 2-7-5(3)]
- C.13 General Reporting Requirements [326 IAC 2-7-5(3)(C)]

### Record Keeping and Reporting Requirements [326 IAC 2-7-5(3)][326 IAC 2-7-6] [326 IAC 2-7-19]

- C.12 General Record Keeping Requirements [326 IAC 2-7-5(3)][326 IAC 2-7-6]
- C.13 General Reporting Requirements [326 IAC 2-7-5(3)(C)]

### Comment 6:

D.1 should not include reference to the pharmaceutical process (it has been removed from the body of

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the permit).

### **Response to Comment 6:**

Reference was removed.

- D.1 FACILITY OPERATION CONDITIONS One (1) subbituminous coal fired boiler . 11

### Comment 7:

D.1.1 is incorrectly numbered as D.1.4.

### **Response to Comment 7:**

Numbering was corrected.

- D.1.4 Fuel Use Limitation [326 IAC 2-7-10.5(d)(5)]
- D.1.1 Fuel Use Limitation [326 IAC 2-7-10.5(d)(5)]

### Comment 8:

D.1.2 contains erroneous references to sulfur dioxide limitations and sulfur content that should be deleted.

### **Response to Comment 8:**

Sulfur dioxide language was removed.

- D.1.2 Sulfur Dioxide (SO<sub>2</sub>) Emissions and Sulfur Content and Hydrogen Chloride (HCl) Emissions and Chlorine (Cl) Content [326 IAC 7-2]
- D.1.2 Hydrogen Chloride (HCI) Emissions and Chlorine (CI) Content [326 IAC 7-2]

### SECTION A.

### Comment 9:

### Condition A.2

The term "miscellaneous" is misspelled and should include a reference to the insignificant activity emissions described in Condition A.3. See proposed revision in attached redline excerpts from the draft permit.

### **Response to Comment 9:**

Typo was corrected and reference was added.

This approval establishes a limitation on the chlorine content of coal fed to boiler #8 which, combined with the miscelaneous emissions described in Condition A.3, will restrict Pfizer Inc's potential emissions to below the minimum thresholds for a major source for Hazardous Air Pollutants (HAP).

This approval establishes a limitation on the chlorine content of coal fed to boiler #8 which, combined with the **miscellaneous** emissions described in Condition A.3, will restrict Pfizer Inc's potential emissions to below the minimum thresholds for a major source for Hazardous Air

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Pollutants (HAP).

### Comment 10:

### Condition A.3

The introductory paragraph should include a cross reference identifying the listed insignificant activities to "miscellaneous emissions". See attached redlined draft permit.

### **Response to Comment 10:**

Reference was added.

This stationary source also includes the following insignificant activities which are specifically regulated, as defined in 326 IAC 2-7-1(21).

This stationary source also includes the following insignificant activities which are specifically regulated, as defined in 326 IAC 2-7-1(21). Potential emissions of HCI from these insignificant activities are referred to, for purposes of this approval, as the "miscellaneous emissions":

SECTION B.

### Comment 11:

### Condition B.3

B.3 is not needed since there is no construction involved in this approval as referenced by 326 IAC 2-1.1-9's

revocation provisions and the Part 70 rules.

### **Response to Comment 11:**

This condition is for a modification which includes construction. This modification does not include any construction. Therefore, condition B.3 will be deleted.

B.3 Revocation of Permits [326 IAC 2-1.1-9(5)][326 IAC 2-7-10.5(i)]

Pursuant to 326 IAC 2-1.1-9(5)(Revocation of Permits), the Commissioner may revoke this approval if construction is not commenced within eighteen (18) months after receipt of this approval or if construction is suspended for a continuous period of one (1) year or more.

### Comment 12:

### Condition B.4.

The language of Condition B.4, which is drawn from 326 IAC 2-7-10.5(h), is not readily applied to the context of this significant source modification, which involves only a change in method of operation (1.3., restricting coal input to boiler 8 to produce HCl emissions below major source levels) rather than the construction of new emission units. Boiler 8 is already in operation but the proposed permit language could be construed to preclude its operation until an affidavit of construction is submitted. The language of subsection (h) should be susceptible to application to the current context in a manner similar to that proposed in the attached redline permit document.

### **Response to Comment 12:**

This condition is for a modification which includes construction. This modification does not include any construction. Therefore, those portions of condition B.4 related to construction will be deleted.

### B.4 Significant Source Modification [326 IAC 2-7-10.5(h)]

This document shall also become the approval to operate pursuant to 326 IAC 2-7-10.5(h) when, prior to start of operation, the following requirements are met:

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(a) The attached affidavit of construction shall be submitted to the Office of Air Quality (OAQ), Permit Administration & Development Section, verifying that the emission units were constructed as proposed in the application. The emissions units covered in the Significant Source Modification approval may begin operating on the date the affidavit of construction is postmarked or hand delivered to IDEM if constructed as proposed.

- (b) If actual construction of the emissions units differs from the construction proposed in the application, the source may not begin operation until the source modification has been revised pursuant to 326 IAC 2-7-11 or 326 IAC 2-7-12 and an Operation Permit Validation Letter is issued.
- (c) If construction is completed in phases; i.e., the entire construction is not done continuously, a separate affidavit must be submitted for each phase of construction.

  Any permit conditions associated with operation start up dates such as stack testing for New Source Performance Standards (NSPS) shall be applicable to each individual phase.
  - (d) The Permittee shall receive an Operation Permit Validation Letter from the Chief of the Permit Administration & Development Section and attach it to this document.
    - (a) In the event that the Part 70 application is being processed at the same time as this application, the following additional procedures shall be followed for obtaining the right to operate:
      - (1) If the Part 70 draft permit has not gone on public notice, then the change/addition covered by the Significant Source Modification will be included in the Part 70 draft.
      - (2) If the Part 70 permit has gone through final EPA proposal and would be issued ahead of the Significant Source Modification, the Significant Source Modification will go through a concurrent 45 day EPA review. Then the Significant Source Modification will be incorporated into the final Part 70 permit at the time of issuance.
      - (3) If the Part 70 permit has gone through public notice, but has not gone through final EPA review and would be issued after the Significant Source Modification is issued, then the Modification would be added to the proposed Part 70 permit, and the Title V permit will issued after EPA review.

### SECTION C.

### Comment 13:

Condition C.2 does not apply since there is no requirement in Section D for preparation of a PMP. Thus, Pfizer suggests that C.2 be deleted from the approval.

### **Response to Comment 13:**

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The condition states that it applies only if there are any requirements in Section D. There are no requirements for this to apply due to no requirements in Section D. This condition will be deleted.

C.2 Preventive Maintenance Plan [326 IAC 2-7-5(1),(3) and (13)] [326 IAC 2-7-6(1) and (6)] [326 IAC 1-6-3]

(a) If required by specific condition(s) in Section D of this permit, the Permittee shall prepare and maintain Preventive Maintenance Plans (PMPs) when operation begins, including the following information on each facility:

(1) Identification of the individual(s) responsible for inspecting, maintaining, and

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	repairing emission control devices;
	(2) A description of the items or conditions that will be inspected and the inspection schedule for said items or conditions; and
	(3) Identification and quantification of the replacement parts that will be maintained in inventory for quick replacement.
	If, due to circumstances beyond the Permittee's control, the PMPs cannot be prepared and maintained within the above time frame, the Permittee may extend the date an additional ninety (90) days provided the Permittee notifies:
	Indiana Department of Environmental Management Compliance Branch, Office of Air Quality 100 North Senate Avenue, P. O. Box 6015 Indianapolis, Indiana 46206-6015
	<del>and</del>
	Vigo County Air Pollution Control 103 South Third Street Terre Haute, Indiana 47807
	The PMP and the PMP extension notification do not require the certification by the "responsible official" as defined by 326 IAC 2-7-1(34).
(b)	The Permittee shall implement the PMPs as necessary to ensure that failure to implement a PMP does not cause or contribute to a violation of any limitation on emissions or potential to emit.
<del>(c)</del>	A copy of the PMPs shall be submitted to IDEM, OAQ, and VCAPC upon request and within a reasonable time, and shall be subject to review and approval by IDEM, OAQ, and VCAPC. IDEM, OAQ, and VCAPC may require the Permittee to revise its PMPs whenever lack of proper maintenance causes or contributes to any violation. The PMP does not require the certification by the "responsible official" as defined by 326 IAC 2-7-1(34).
<del>(a)</del>	Records of preventive maintenance shall be retained for a period of at least five (5) years. These records shall be kept at the source location for a minimum of three (3) years. The records may be stored elsewhere for the remaining two (2) years as long as they are available upon request. If the Commissioner or VCAPC makes a request for records to the Permittee, the Permittee shall furnish the records to the Commissioner or

### Comment 14:

Condition C.9 has a typo in the citation that should read as 326 IAC 2-7-5(3) in the heading.

### **Response to Comment 14:**

Typo was corrected.

Compliance Monitoring Requirements [326 IAC 2-7-5(1)] [326 IAC 2-7-6(1)]

Compliance Monitoring Requirements [326 IAC 2-7-5(3)] [326 IAC 2-7-6(1)]

### Comment 15:

Condition C.10 should include a citation reference to 326 IAC 2-7-16.

VCAPC within a reasonable time.

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### **Response to Comment 15:**

Reference was added.

Corrective Actions and Response Steps [326 IAC 2-7-5] [326 IAC 2-7-6]

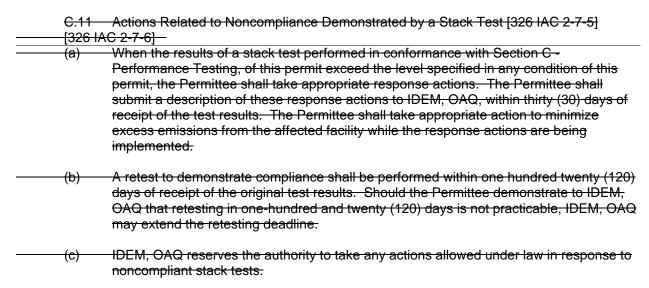
Corrective Actions and Response Steps [326 IAC 2-7-5] [326 IAC 2-7-6][326 IAC 2-7-16]

### Comment 16:

C.11, paragraph (a) references a "Section C - Performance Testing". However, there is no such provision in Section C.

### **Response to Comment 16:**

There are no stack tests required by this permit. Therefore, Condition C.11 will be deleted.



The documents submitted pursuant to this condition do not require the certification by the "responsible official" as defined by 326 IAC 2-7-1(34).

### Comment 17:

Record keeping and Reporting Requirements - a reference to 326 IAC 2-7-6 should be added.

### **Response to Comment 17:**

Reference was added.

Record Keeping and Reporting Requirements [326 IAC 2-7-5(3)][326 IAC 2-7-19]

Record Keeping and Reporting Requirements [326 IAC 2-7-5(3)] [326 IAC 2-7-6][326 IAC 2-7-19]

### Comment 18:

Condition D.1.1.

Minor rewording of paragraph (b) is suggested. See attached redline version of draft SSM.

### **Response to Comment 18:**

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Paragraph (b) was reworded.

(b) This limitation, in combination with the miscellaneous emissions, keeps the potential emissions below 10 tons per year of HCl. Therefore, Pfizer Inc is not considered a major source for Hazardous Air Pollutants (HAPs) and is not subject to 40 CFR Part 63, Subpart GGG National Emission Standards for Pharmaceuticals Production, or any other NESHAP.

(b) This limitation, in combination with the miscellaneous emissions, **restricts** keeps the potential emissions **of HCI** below 10 tons per year <del>of HCI</del>. Therefore, Pfizer Inc is not considered a major source for Hazardous Air Pollutants (HAPs) and is not subject to 40 CFR Part 63, Subpart GGG National Emission Standards for Pharmaceuticals Production, or any other NESHAP.

### Comment 19:

### Condition D.1.2.

The introductory paragraph should be rewritten to track Condition D.1.1, which limits chlorine input to Boiler 8 rather than HCl emissions. See attached redline version of draft SSM. The reference to 326 IAC 7-2, which pertains to sulfur dioxide limitations, should be deleted. 326 IAC 2-7-6 should be referenced.

### **Response to Comment 19:**

The introductory paragraph was rewritten since the limit was changed from HCl emissions to chlorine content. The reference was changed from 326 IAC 7-2 to 326 IAC 2-7-6.

D.1.2 Hydrogen Chloride (HCI) Emissions and Chlorine Content [326 IAC 7-2]

Pursuant to 32 6 IAC 7-2, the Permittee shall demonstrate that the hydrogen chloride (HCI) emissions from Boiler #8 shall not exceed 9.43 tons per year. Compliance shall be determined utilizing one of the following options:

D.1.2 Hydrogen Chloride (HCI) Emissions and Chlorine Content [326 IAC 7-2]

Pursuant to 326 IAC—7-2 2-7-6, the Permittee shall demonstrate that the hydrogen chloride (HCl) emissions from chlorine content of coal delovered to Boiler #8 shall does not exceed the limitation set in Condition D.1.1 (9.43 tons per year 12-consecutive month period). Compliance shall be determined utilizing one of the following options:

### Comment 20:

Condition D.1.3.

Paragraph (a) should be revised to refer to the chlorine content limit on coal input to the boiler rather than an HCL emission limit in order to accurately track Condition D.1.1.

### **Response to Comment 20:**

Paragraph (a) was revised to refer to the chlorine content instead of the HCl emission limit.

### D.1.3 Record Keeping Requirements

(a) To document compliance with Condition D.1.1, the Permittee shall maintain records for Boiler #8 in accordance with (1) through (4) below. Records maintained for (1) through (4) shall be taken monthly and shall be complete and sufficient to establish compliance with the Hydrogen Chloride (HCl) emissions limit in D.1.1.

- (1) Calendar dates covered in the compliance determination period;
- (2) Actual coal usage since last compliance determination period;
- (3) Chlorine content, heat content, and ash content (as received basis);

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- (4) Chlorine input during compliance period
- (5) Hydrogen Chloride emission rates.
- (b) Pursuant to 326 IAC 3-7-5(a), the Permittee has developed a standard operating procedure (SOP) to be followed for sampling, handling, analysis, quality control, quality assurance, and data reporting of the information collected pursuant to 326 IAC 3-7-2 through 326 IAC 3-7-4. Any revision to the SOP shall be submitted to IDEM, OAQ and VCAPC.

### D.1.3 Record Keeping Requirements

- (a) To document compliance with Condition D.1.1, the Permittee shall maintain records for Boiler #8 in accordance with (1) through (4) below. Records maintained for (1) through (4) shall be taken monthly and shall be complete and sufficient to establish compliance with the Hydrogen Chloride (HCI) emissions limit on chlorine content of coal combusted in Boiler #8 in D.1.1.
  - (1) Calendar dates covered in the compliance determination period;
  - (2) Actual coal usage since last compliance determination period;
  - (3) Chlorine content, heat content, and ash content (as received basis);
  - (4) Chlorine input during compliance period
  - (5) Hydrogen Chloride emission rates.
- (b) Pursuant to 326 IAC 3-7-5(a), the Permittee has developed a standard operating procedure (SOP) to be followed for sampling, handling, analysis, quality control, quality assurance, and data reporting of the information collected pursuant to 326 IAC 3-7-2 through 326 IAC 3-7-4 3. Any revision to the SOP shall be submitted to IDEM, OAQ and VCAPC.

On October 11, 2002, Larry Kane (Pfizer Inc's legal representative) submitted the following comment on the proposed Significant Source Modification. The comment is as follows:

### Comment 21:

Condition B.3 (originally B.4)

The first sentence should be revised to make it more clear that Pfizer is authorized to commence operations under the SSM immediately upon its issuance. Otherwise, we're left with uncertainty as to when Pfizer may operate.

### **Response to Comment 21:**

Condition B.3 was revised with Larry's suggested language.

### B.3 Significant Source Modification [326 IAC 2-7-10.5(h)]

This document shall also become the approval to operate pursuant to 326 IAC 2-7-10.5(h) when, prior to start of operation, the following requirements are met:

### B.3 Significant Source Modification [326 IAC 2-7-10.5(h)]

This document shall also become the approval to operate pursuant to 326 IAC 2-7-10.5(h) when, prior to start of operation, the following requirements are met: Since no construction is planned under the Significant Source Modification, this document shall also become the approval to operate effective upon its issuance.

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Terre Haute, Indiana Source Modification Number: 167-15658-00013

Permit Reviewer: Darren Woodward

### Comment 22:

Response to Comment 19 had a typo.

D.1.2 Hydrogen Chloride (HCl) Emissions and Chlorine Content [326 IAC 7-2]

Pursuant to 326 IAC<del>-7-2</del> **2-7-6**, the Permittee shall demonstrate that the hydrogen chloride (HCl) emissions from chlorine content of coal delovered delivered to Boiler #8 shall does not exceed the limitation set in Condition D.1.1 (9.43 tons per year 12-consecutive month period). Compliance shall be determined utilizing one of the following options:

### Comment 23:

Condition D.1.3 has two typo's in paragraph (a).

### **Response to Comment 23:**

Typo's were corrected.

- (a) To document compliance with Condition D.1.1, the Permittee shall maintain records for Boiler #8 in accordance with (1) through (4)(5) below. Records maintained for (1) through (4)(5) shall be taken monthly and shall be complete and sufficient to establish compliance with the limit on chlorine content of coal combusted in boiler #8.
  - (1) Calendar dates covered in the compliance determination period;
  - (2) Actual coal usage since last compliance determination period;
  - (3) Chlorine content, heat content, and ash content (as received basis):
  - (4) Chlorine input during compliance period
  - (5) Hydrogen Chloride emission rates.

### Comment 24:

Parts (a) and (d) of Comment/Response 12 could stay in the modification.

### **Response to Comment 24:**

Parts (a) and (d) remained in the modification.

### Indiana Department of Environmental Management Office of Air Quality and Vigo County Air Pollution Control

Technical Support Document (TSD) for a Significant Source Modification to a Draft Part 70 Operating Permit

### **Source Background and Description**

Source Name: Pfizer Inc

Source Location: 100 Pfizer Drive, Terre Haute, Indiana 47802

County: Vigo SIC Code: 2833

Draft Operation Permit No.: 167-7586-00013
Operation Permit Issuance Date: not yet issued
Permit Modification No.: 167-15658-00013
Permit Reviewer: Darren Woodward

The Office of Air Quality (OAQ) and Vigo County Air Pollution Control (VCAPC) has reviewed a modification application from Pfizer Inc relating to the operation of a coal-fired boiler at its stationary pharmaceutical manufacturing facility.

### **Explanation of Modification**

Pfizer has requested issuance of a Significant Source Modification before October 21, 2002, the Pharmaceutical MACT compliance deadline, for an enforceable emission limitation of hydrogen chloride (HCI) which will make Pfizer's source a synthetic minor with respect to emission of HAPs. None of the other various HAPs emitted by the combustion of coal in the boiler show that a significant level of emissions will be reached. Therefore, hydrogen chloride is the only HAP to be examined here.

### Justification for the Modification

The Draft Part 70 Operating permit is being modified through a Part 70 Significant Source Modification. This modification is being performed pursuant to 326 IAC 2-7-10.5(d)(5).

The HCI emissions come from the operation of Boiler #8 and from various miscellaneous minor and insignificant facilities. The minor facilities include bioprocessing, laboratories, cleaning and maintenance, and wastewater operations. These minor facilities amount to approximately 0.3 tons of HCI per year. There are no other facilities with single HAP emissions greater than 10 tons per year or a combination of HAP emissions greater than 25 tons per year. Therefore, to prevent the HCI emissions form being greater than 10 tons per year, the Boiler #8 's HCI emissions would have to be held to less than 9.7 (10 - 0.3) tons per year.

Activity	Pounds Emitted Actual	Pounds Emitted Potential
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Terre Haute, Indiana Source Modification No.: 167-15658-00013

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Bioprocessing - tanks	25.67	32.08	
Bioprocessing - fugitive	119.00	119.00	
Laboratories	0.32	1.75	
Cleaning	175.30	350.59	
Wastewater	0.00	0.00	
TOTAL	320.28	503.43	

The coal contains levels of chlorine (CI) that forms hydrogen chloride when the coal is burned. Therefore, the content must be limited to stay below the singular HAP threshold. The weight limit on Chlorine in the coal combusted is determined by multiplying the desired HCL limit (9.7 TPY) by the ratio of the molecular weight of Chlorine to the molecular weight of Hydrogen Chloride (35.5/36.5). The limit is 9.43 TPY Chlorine in the coal combusted. This limitation, in combination with the miscellaneous emissions, keeps the potential emissions below (10) tons per year of HCI. Therefore, Pfizer Inc is not considered a major source for Hazardous Air Pollutants (HAPs) and is not subject to 40 CFR Part 63, Subpart GGG National Emission Standards for Pharmaceuticals Production, or any other NESHAP.

The Chlorine content of coal samples shall be determined in accordance with either the procedures specified in ASTM D2361, Standard Test Methods for Chlorine in Coal, or the procedures specified in ASTM D4208, Standard Test Method for Total Chlorine in Coal by the Oxygen Bomb Combustion/Ion Selective Electrode Method.

### Recommendation

The staff recommends to the Commissioner that the Significant Source Modification be approved. This recommendation is based on the following facts and conditions:

Unless otherwise stated, information used in this review was derived from the application and additional information submitted by the applicant.

An application for the purposes of this review was received on May 21, 2002. Additional information was received on August 2, 2002.

### Conclusion

This source modification shall be subject to the conditions of the attached **Significant Source Modification No. 167-15658-00013**.

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Source Name: Pfizer Inc

Source Location: 100 Pfizer Drive, Terre Haute, Indiana 47802

County: Vigo SIC Code: 2833

Source Modification No.: 167-15658-13

Limitation: Limiting amount of Chlorine input to 9.43 tons (which will limit HCl emissions to 9.7 tons/yr)

Permit Reviewer: Darren Woodward

### **Calculations**

Molecular wt of Cl = 35.5 Molecular wt of HCl= 36.5 Limitation = 9.7 TPY HCl

Chlorine input (TPY)= 9.7 TPY X <u>35.5</u> 36.5

Chlorine input (TPY)= 9.43 TPY

Source Name: Pfizer Inc

Source Location: 100 Pfizer Drive, Terre Haute, Indiana 47802

County: Vigo SIC Code: 2833

Source Modification No.: 167-15658-00013 Reviewer: Darren Woodward

Coal Combustion HAPs	38000	38000 tons		
<u>pollutant</u>	<u>lb/ton</u>	<u>pounds</u>	<u>tons</u>	
Acetaldehyde	5.70E-04	2.17E+01		
Acrolein	2.90E-04	1.10E+01	5.51E-03	
Benzene	1.30E-03	4.94E+01	2.47E-02	
Benzyl chloride	7.00E-04	2.66E+01	1.33E-02	
Bis(2-ethylhexl)phthalate (DEHP)	7.30E-05	2.77E+00	1.39E-03	
Bromoform	3.90E-05	1.48E+00	7.41E-04	
Carbon disulfide	1.30E-04	4.94E+00	2.47E-03	
Chloroform	5.90E-05	2.24E+00	1.12E-03	
Dimethyl sulfate	4.80E-05	1.82E+00	9.12E-04	
Ethyl benzene	9.40E-05	3.57E+00	1.79E-03	
Ethyl chloride	4.20E-05	1.60E+00	7.98E-04	
Ethylene dichloride	4.00E-05	1.52E+00	7.60E-04	
Formaldehyde	2.40E-04	9.12E+00	4.56E-03	
Hexane	6.70E-05	2.55E+00	1.27E-03	
Isophorone	5.80E-04	2.20E+01	1.10E-02	
Methyl bromide	1.60E-04	6.08E+00	3.04E-03	
Methyl chloride	5.30E-04	2.01E+01	1.01E-02	
Methyl ethyl ketone	3.90E-04	1.48E+01	7.41E-03	
Methyl hydrazine	1.70E-04	6.46E+00	3.23E-03	
Methyl tert butyl ether	3.50E-05	1.33E+00	6.65E-04	
Methylene chloride	2.90E-04	1.10E+01	5.51E-03	
Propionaldehyde	3.80E-04	1.44E+01	7.22E-03	
Tetrachloroethylene	4.30E-05	1.63E+00	8.17E-04	
Toluene	2.40E-04	9.12E+00	4.56E-03	
Xylenes	3.70E-05	1.41E+00	7.03E-04	
Hydrogen Chloride	1.20E+00	4.56E+04	2.28E+01	
Hydrogen Floride	1.50E-01	5.70E+03	2.85E+00	
Selenium	1.30E-03	4.94E+01	2.47E-02	

The HAPs that have emissions of greater than 1 pound/year were the only ones listed.

This is just a demonstration using 38,000 tons per year of coal to show Pfizer's minor amounts of HAPs.